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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,199	09/24/2001	Mitsuaki Yamamoto	213966US0PCT	6427
22850	7590	02/07/2006	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			FOSTER, CHRISTINE E	
1940 DUKE STREET			ART UNIT	
ALEXANDRIA, VA 22314			PAPER NUMBER	

1641

DATE MAILED: 02/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/926,199	YAMAMOTO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Christine Foster	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) 46-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 31-45 and 61 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. Applicant's amendment, filed 12/5/05 is acknowledged and has been entered.

Claims 1-30 have been cancelled.

Claims 31-61 have been added.

### *Election/Restrictions*

2. Newly submitted claims 46-60 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the Office has previously required restriction between methods of quantitating cholesterol and reagents for quantitating cholesterol, which were shown to lack unity of invention (see the Office action mailed 6/17/05 at p. 2-3). The claims directed to methods of quantitating cholesterol do not read on the elected invention of a **reagent comprising a compound having a relatively strong affinity with non-measuring lipoproteins** (see Applicant's response of 7/18/05 at p. 1).

Since Applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-60 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

### *Supplemental Election/Restrictions*

3. The elected invention of a **reagent comprising a compound having a relatively strong affinity with non-measuring lipoproteins** now appears to be presented by Applicant as newly submitted claims 31-45 and 61, which recite reagents comprising a compound having a stronger

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affinity with any lipoproteins except HDL than with HDL. Numerous types of compounds are now claimed, which were not recited in original claim 18. If the claims as originally filed had been presented as such, they would have been properly subject to an election of species.

Therefore, a Supplemental requirement for Election/Restriction is presented below.

4. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Applicant is required to elect a single **compound** having stronger affinity with any lipoproteins except HDL than with HDL (elect one of the following):

a. Saponins

*Note:* In the event that “saponins” are elected, Applicant is also required to elect a single compound from the following list (see claim 40):

(1) Digitonin

(2) Tomatine

b. Polyenes

*Note:* In the event that “polyenes” are elected, Applicant is also required to elect a single compound from the following list (see claim 41):

(1) Nystatin

(2) Filipin

(3) Pimacillyn

(4) Pentamycin

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- (5) Trichomycin
- (6) Fungichromin
- (7) Perimycin
- (8) Amphotericin
- (9) Etoluscomycin
- (10) Primycin
- (11) Candigin

b. Cholesterol derivatives

*Note:* In the event that “cholesterol derivatives” are elected, Applicant is also required to elect the following compound (see claim 42):

- (1) [N-[2-cholesterylcarboxyamino)ethyl]carbamoymethyl]-pullalan

b. Phospholipid derivatives

*Note:* In the event that “phospholipid derivatives” are elected, Applicant is also required to elect the following compound (see claim 43):

- (1) L- $\alpha$ -phosphatidyl glycerol dipalmitoyl

b. Bacitracin

c. Polymyxin

d. Suzycasylin

e. Gramicidin

f. Lectins

*Note:* In the event that “lectins” are elected, Applicant is also required to elect a **single** type of lectin. Election may be made by specifying a type of lectin by

name, e.g. “concanavalin A”, and by indicating in the specification where support may be found for such a compound.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

5. The claims are deemed to correspond to the species listed above in the following manner:

The following claim(s) are generic: Claims 31 and 44-45.

Claims 32 and 40 correspond to the species of **Saponins**.

Claims 33 and 41 correspond to the species of **Polyenes**.

Claims 34 and 42 correspond to the species of **Cholesterol derivatives**.

Claims 35 and 43 correspond to the species of **Phospholipid derivatives**.

Claim 36 corresponds to the species of **Bacitracin**.

Claim 37 corresponds to the species of **Polymyxin**.

Claim 38 corresponds to the species of **Suzycasylin**.

Claim 39 corresponds to the species of **Gramicidin**.

Claim 61 corresponds to the species of **Lectins**.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity and a common structure that is a significant structural element. The chemical compounds recited in claims 31-45 and 61 are not regarded as being of similar nature because they do not possess a common property or activity and do not share a common structure that is a significant structural element. Each of the above compounds represent structurally, chemically, and functionally distinct molecules. The structures, physicochemical properties, reactivities, and modes of action of these molecules are different, and they do not share a common structure that is disclosed to be essential for common utility. The compounds span varying chemical classes, including saponins, polyenes, cholesterol derivatives, phospholipids derivatives, and lectins.

6. A telephone call was made to James Kelly on 1/20/06 to request an oral election to the above restriction requirement and a draft copy of the above was faxed on 1/23/06, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

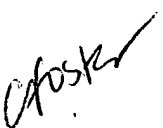
7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

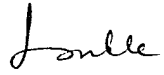
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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine Foster whose telephone number is (571) 272-8786. The examiner can normally be reached on M-F 8:30-5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached at (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
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02/03/06